- Proposal to Change Allocation of Pediatric Lungs and Allow Creation of a Stratified Allocation System for 0-11 Year-Old Candidates (Modifying Policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation) and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation))
- Sponsoring Committees: Pediatric and Thoracic Organ Transplantation Committees
- In July 2006, the Pediatric Transplantation Committee was charged with developing a plan to reduce the number of deaths on the pediatric organ transplant waiting lists. This proposal is one of a series of organ specific proposals resulting from this charge. In keeping with the principles of the Final Rule, the common theme of these proposals is to allocate organs from young pediatric donors more broadly to ensure they are offered first to candidates at highest risk of waiting list mortality, without negatively impacting adults or adolescents. The following policy recommendation specifically addresses allocation to young pediatric lung candidates (defined here as age 0-11 yrs). In order to improve allocation to the sickest young pediatric candidates, two policy changes are proposed. The first would create a simple status system for young pediatric candidates (based on objective medical characteristics) to direct donor lungs to the sickest of these candidates first. The second component would improve access to organs for the sickest patients by more broadly sharing young pediatric donor lungs, allocating first to combined local, Zone A and Zone B young pediatric candidates, and then to combined local and Zone A adolescents before local offers are made to adults. Because historically, only 0.4% of adults received a lung transplant from young pediatric (<12) donors (size matching limits suitability of these donors for adults), we anticipate that these proposed changes will have a limited impact on adults while reducing pediatric waiting list mortality.

Affected groups:

Pediatric Lung Candidates, Public, OPO Executive Directors, OPO Medical Directors, OPO PR/Public Education Staff, OPO Procurement Coordinators, Transplant Administrators, Transplant Coordinators, Transplant PR/Public Education Staff

• Specific requests for comment:

For transplant coordinators and physicians:

- Do you feel that expanding the first round of offers (combining local, Zone A and Zone B offers for 0-11 year-olds and local and Zone A offers for adolescents) has the potential to reduce deaths on the pediatric lung waiting list?
- Do you agree that, because of the small number of 0-11 year-old pediatric lung candidates, a two tiered Status-based system is an appropriate initial step?
- O Do you foresee any negative impacts of this change i.e. potential for increased travel to recover lungs?

For all readers: Please consider and comment on the <u>entire</u> proposal. Please do not feel limited to the focused questions. They are meant only to point out key issues within the proposal that may be of specific interest to some readers.

Proposal to Change Allocation of Pediatric Lungs and Allow Creation of a Stratified Allocation System for 0-11 Year-Old Candidates (Modifying Policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation) and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation))

Sponsoring Committees: Pediatric and Thoracic Organ Transplantation Committees

**NOTE TO READER: Color figures were required to clearly depict the data referenced in this proposal. Color figures may be viewed on-line at www.unos.org or www.optn.org.

Summary and Goals:

In July 2006, the Pediatric Transplantation Committee was charged with developing a plan to reduce the number of deaths on the pediatric organ transplant waiting lists. This proposal is one of a series of organ specific proposals resulting from this charge. In keeping with the principles of the Final Rule, the common theme of these proposals is to allocate organs from young pediatric donors more broadly to ensure they are offered first to candidates at highest risk of waiting list mortality, without negatively impacting adults or adolescents. The following policy recommendation specifically addresses allocation to young pediatric lung candidates (defined here as age 0-11 yrs). In contrast to the lung allocation system (LAS) that in May 2005 began prioritizing adolescent (aged 12 to 17) and adult (aged 18 and older) candidates on the waiting list by a combination of waiting list mortality and predicted survival benefit, allocation to young pediatric candidates continues to be based on waiting time within each allocation zone and blood type. In order to improve allocation to the sickest young pediatric candidates, two policy changes are being proposed. The first would create a simple status system for young pediatric candidates (based on objective medical characteristics) to direct donor lungs to the sickest of these candidates first. The second component would improve access to organs for the sickest patients by more broadly sharing young pediatric donor lungs, allocating first to combined local, Zone A and Zone B young pediatric candidates, and then to combined local and Zone A adolescents before local offers are made to adults. Because historically, only 0.4% of adults received a lung transplant from young pediatric (<12) donors (size matching limits suitability of these donors for adults), we anticipate that these proposed changes will have a limited impact on adults while reducing pediatric waiting list mortality.

Background and Significance:

In July 2006, the Pediatric Transplantation Committee was charged by then OPTN/UNOS President Sue McDiarmid, MD with reducing deaths on the pediatric organ transplantation waiting lists. To most effectively address this charge, the Committee Chair tasked the Committee's Organ Specific Working Groups to consider ways that pediatric waiting list mortality might be reduced within each organ specialty. Each working group:

- Reviewed waiting list mortality to identify and prioritize groups of candidates at risk;
- Reviewed potential causes of higher mortality in an effort to prioritize the areas of intervention most likely to yield benefit;
- Considered current allocation policy, policy initiatives and donor distribution patterns to determine whether simple changes such as broader sharing could be made without impacting waiting list mortality or post-transplant outcomes for adolescents and adults; and
- Defined metrics necessary to measure the impact of any interventions on both the pediatric and adult populations.

Early data and concept proposals were shared with the larger pediatric transplant community during the March 2007, Summit on Pediatric Organ Donation and Transplantation, a collaborative event cosponsored by the United Network for Organ Sharing, the Organ Donation and Transplantation Alliance, and Health Resources and Services Administration. This event provided the Working Groups with an opportunity to share their ideas while receiving feedback from participants of the Summit's Physician and Surgeon track as well as brainstorming for any new concepts regarding:

- (1) Improving access to transplant;
- (2) Doing more with the donors we have- pushing the envelope on size mismatch, distance travelled, pulmonary toilet to improve marginal donors;
- (3) Considering the potential for donation after cardiac death (DCD) donors for pediatric candidates;
- (4) Identifying simple and innovative changes to allocation policy to offer organs first to candidates who will benefit most; and
- (5) Considering critical transplant outcome data.

The Heart-Lung Working Group's ideas were well received at The Summit, and its members continued to meet and further develop ideas on how to improve opportunities for transplant of these youngest candidates.

The Committee shared its analyses with the Thoracic Organ Transplantation Committee during its October 2, 2007, meeting with a goal of building consensus with the adult community prior to public comment. Thoracic Committee members were supportive of the concept of broader sharing of the small lungs and agreed to review the Pediatric Committee's proposal in more detail in an upcoming Heart-Lung Subcommittee meeting that would be treated as a Joint Subcommittee, representing both Thoracic and Pediatric membership.

During its November 29, 2007, meeting Pediatric Committee members reviewed a table comparing current lung allocation policy versus suggested modifications developed by Working Group members. In May 2005, the method for allocating lungs in the United States was modified. For adolescent (aged 12-17) and adult (aged 18 and older) candidates on the waiting list, allocation by waiting time was replaced by the lung allocation system (LAS). The LAS score, calculated using each individual's medical information, prioritizes candidates based on a combination of waiting list mortality and predicted survival benefit. For young pediatric candidates, however, within each allocation zone and blood type, lungs remain allocated based on waiting time. The Working Group's proposal specifically addresses allocation to young pediatric lung candidates (defined here as age 0-11 yrs).

There are two components to these proposed policy changes:

(1) The first would create a simple status system for young pediatric candidates (based on objective medical characteristics) to direct donor lungs to the sickest of these candidates first. Pediatric lung programs were informally polled regarding all current and recent candidates to determine where they fell into the two categories below:

Status 1: candidates with one or more of the following criteria:

- Respiratory failure, defined as:
 - Full time Mechanical Ventilation;

- \circ Supplemental oxygen delivered by any means to achieve FiO₂ > 50% necessary to maintain oxygen saturation > 90%;
- Arterial or capillary $PCO_2 > 50$.

• Refractory pulmonary hypertension, defined as:

- Treatment failure (any of: suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate, cardiac index < 2, recurrent syncope or hemoptysis) while on 2 or more drug therapy;
- o patients with pulmonary vein stenosis involving 3 or more vessels.

Exceptional cases by prospective submission to a review board

Status 2: all remaining candidates

Youngest patients were more likely to be classified as Status 1, as expected, and the numbers of candidates likely to be offered any given donor was likely to be small enough that a more complex stratification would not be needed. Such a system was agreed upon as expected to move the sickest 0-11 year-olds to the top of the match run in much the same way that LAS functions for adolescents and adults.

Additional data will be required to establish status classification for 0-11 year-old lung candidates. The Pediatric Heart-Lung Working Group is working with UNOS IT Development staff to integrate data collection into the current mechanism used by the LAS to collect the required and optional listing data elements. Several of these variables are already part of the clinical data required to assign LAS scores for adolescent and adult lung candidates, and many pediatric programs already enter their 0-11 year-old candidates' clinical data related to the lung allocation score, though it is not required. The Pediatric Committee is currently studying the feasibility of adding elements required for the proposed status system that are not already captured in LAS, and making all status-related clinical data mandatory for these 0-11 year-old candidates. The Joint Subcommittee will consider feedback from IT Development staff and recommend a collection method when the Board considers this proposal.

This new status system would follow requirements for LAS, allowing programs to update their candidates' clinical data at any time they believe a change in candidate medical condition warrants such modification. Programs must update every candidate variable for each candidate at least once every six months. If at any time, more than six months have elapsed since the last six-month "anniversary" date of the candidate's initial listing without an update, then the candidate's status will automatically revert to Status 2.

Currently, when a candidate reaches the age of 12, he or she is given an LAS score and located lungs based upon that score. This will not change with the introduction of status for candidates initially listed as aged less than 12.

UNOS staff will establish a plan for Lung Review Board (LRB) consideration of exceptional cases submitted prospectively for 0-11 year old candidates. The LRB currently has only two pediatric programs represented. One program serves as the primary pediatric representative and the

secondary program reviews pediatric cases from the primary's program. Each of the two programs has a primary reviewer and an alternate for a total of four doctors. This would not be sufficient to adjudicate cases for these 0-11 year-old candidates, so a separate pediatric LRB may be required for this review process.

The second component proposes broader sharing for young pediatric donor lungs, allocating first to a <u>combined</u> group of local, Zone A and Zone B 0-11 year-old pediatric candidates, and then to a <u>combined</u> group of local and Zone A adolescents before local offers are made to adults (as seen in Figure 1, comparing current and proposed allocation policy for 0-11 year-old lung donors). Collapsing offers and eliminating the local category will ensure that the sickest lung candidates will receive offers first. It is not unusual for lung offers to extend out to Zone B for placement due to size using the current system. Because size matching limits suitability of pediatric donors to adults, historically, only 0.4% of adults received a lung transplant from pediatric donors (<12 years). These proposed changes should have a limited impact on adults while reducing pediatric waiting list mortality.

Please note that the geographic order of allocation for adolescent (12- 17 year-old) donors <u>will</u> <u>not</u> be modified.

Figure 1: Current Sequence of Pediatric Donor Lung Allocation and Proposed Changes

Existing Lung Allocation Sequence for 0-11 year-old donors		Proposed Lung Allocation Sequence for 0-11 year-old donors	
Local	1. Ped ¹ . ABO identical, wait time	COMBINED Local, Zone A	1. Ped. ABO ident., Status 1, wait time
I	2. Ped. ABO compatible, wait time	and Zone B	2. Ped. ABO compat., Status 1, wait time
I	3. Adol ² . ABO identical, LAS	/	3. Ped. ABO ident., Status 2, wait time
I	4. Adol. ABO compatible, LAS		4. Ped. ABO compat., Status 2, wait time
1	5. Adult ABO identical, LAS	COMBINED Local and Zone A	5. Adol. ABO identical, LAS
I	6. Adult ABO compatible, LAS		6. Adol. ABO compatible, LAS
I		Local	7. Adult ABO identical, LAS
<u> </u>			8. Adult ABO compatible, LAS
Zone A	7. Ped. ABO identical, wait time	Zope A	9. Adult ABO identical, LAS
I	8. Ped. ABO compatible, wait time		10. Adult ABO compatible, LAS
1	9. Adol. ABO identical, LAS		
I	10. Adol. ABO compatible, LAS		
1	11. Adult ABO identical, LAS	1 /	
<u> </u>	12. Adult ABO compatible, LAS		
Zone B	13. Ped. ABO identical, wait time	Zope B	11. Adol. ABO identical, LAS
I	14. Ped. ABO compatible, wait time	1/	12. Adol. ABO compatible, LAS
I	15. Adol. ABO identical, LAS	ľ	13. Adult ABO identical, LAS
1	16. Adol. ABO compatible, LAS	1	14. Adult ABO compatible, LAS
1	17. Adult ABO identical, LAS	1	·
I	18. Adult ABO compatible, LAS	1	
Zone C	19. Ped. ABO identical, wait time	Zone C	15. Ped. ABO ident., Status 1, wait time
1	20. Ped. ABO compatible, wait time	1	16. Ped. ABO compat., Status 1, wait time
I	21. Adol. ABO identical, LAS	1	17. Ped. ABO ident., Status 2, wait time
1	22. Adol. ABO compatible, LAS	1	18. Ped. ABO compat., Status 2, wait time
I	23. Adult ABO identical, LAS	1	19. Adol. ABO identical, LAS
1	24. Adult ABO compatible, LAS	1	20. Adol. ABO compatible, LAS
I			21. Adult ABO identical, LAS
I			22. Adult ABO compatible, LAS
Zone D	25. Ped. ABO identical, wait time	Zone D	23. Ped. ABO ident., Status 1, wait time
1	26. Ped. ABO compatible, wait time	1	24. Ped. ABO compat., Status 1, wait time
I	27. Adol. ABO identical, LAS	1	25. Ped. ABO ident., Status 2, wait time
1	28. Adol. ABO compatible, LAS		26. Ped. ABO compat., Status 2, wait time
I	29. Adult ABO identical, LAS	1	27. Adol. ABO identical, LAS
1	30. Adult ABO compatible, LAS	1	28. Adol. ABO compatible, LAS
1			29. Adult ABO identical, LAS
I			30. Adult ABO compatible, LAS
Zone E	31. Ped. ABO identical, wait time	Zone E	31. Ped. ABO ident., Status 1, wait time
	32. Ped. ABO compatible, wait time	1	32. Ped. ABO compat., Status 1, wait time
	33. Adol. ABO identical, LAS	1	33. Ped. ABO ident., Status 2, wait time
	34. Adol. ABO compatible, LAS	1	34. Ped. ABO compat., Status 2, wait time
	35. Adult ABO identical, LAS	1	35. Adol. ABO identical, LAS
	36. Adult ABO compatible, LAS	1	36. Adol. ABO compatible, LAS
			37. Adult ABO identical, LAS
İ			38. Adult ABO compatible, LAS

¹ Ped. = age 0-11 years ² Adol. = age 12-17 years

Due to the small number of heart-lung transplants performed each year, the Pediatric Committee agreed that no modifications to the combined heart-lung match should be pursued within this proposal, but may be considered at a later date in conjunction with the Thoracic Committee.

The Working Group met with the Thoracic Committee's Lung Subcommittees as a Joint Subcommittee on January 10, 2008. Members reviewed the proposal and considered the idea of releasing these proposals as a joint effort between the committees to reflect consensus on changing the current allocation algorithm to better serve these young children. Members were supportive of creating a simple status category for the younger pediatric candidates and accepting of the notion of eliminating local allocation to better serve pediatric candidates. While combining local, Zone A and Zone B offers for 0-11 year-old candidates as well as combining Local and Zone A offers for adolescent receiving offers for 0-11 year old donor lungs may be expected to increase the travel burden for recovery teams, overall, it will benefit candidates by increasing offers for those candidates who are sickest. In conjunction with the proposed status system for 0-11 year olds that will be incorporated into lung allocation policy, the Pediatric Committee's charge of reducing waiting list deaths should be achieved. Because only 0.4% of adults received a lung transplant from pediatric (<12) donors upon review of transplants performed during 5/4/05-2/28/07, adults should not be affected by these alterations that combine the traditional offer groups into one larger group for pediatric candidates.

After review and discussion, the Joint Subcommittee voted unanimously (12 yes- 0 no- 0 abstentions) to move forward with circulating a public comment proposal to outline the recommended changes and request feedback from the lung transplant community.

Supporting Evidence/Modeling:

The Pediatric Committee reviewed numerous OPTN analyses over the course of the last year and a half as it determined the best way to address its charge to reduce deaths on the pediatric lung waiting list. Evidence showed that infants have the highest mortality on the lung waiting list when grouped by age, followed by candidates in the 1-5 year old and adolescent age groups (Figure 2).

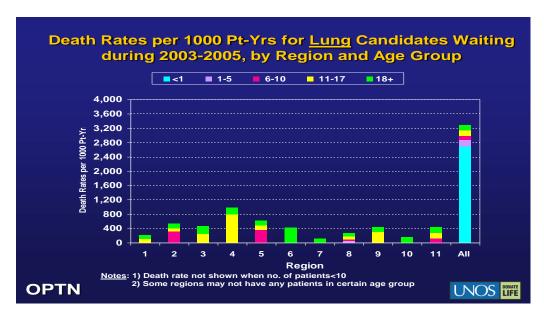


Figure 2: Death Rates per 1000 patient-years on Lung Candidate Waiting list by Region and Age Group, 2003-2005

Though the actual number of pediatric candidates waiting for a lung (or lungs) is small, up to 67% of these candidates are removed from the waiting list as too sick to transplant or due to death while waiting for an organ without ever receiving an lung offer, with infants and adolescents noted as most likely to fall into this category (Figure 3).

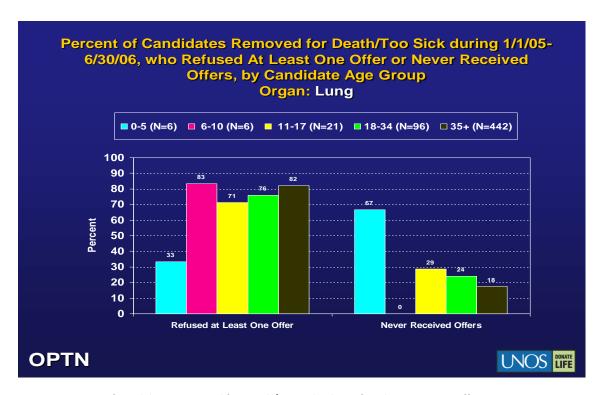


Figure 3: Percent of Candidates Removed for Death/Too Sick who Refused at Least One Offer or Never Received an Offer by Candidate Age Group

The Committee observed that among deceased donor (DD) lung transplants from pediatric donors during the 2005-2006 study period, very small percentage of adults received 8-11 year old-donor lungs, and no adults received a transplant from <8 year old-donor lungs (Figure 4). This information was critical as the Committee developed a proposal to benefit pediatric candidates without disadvantaging adolescents or adults.

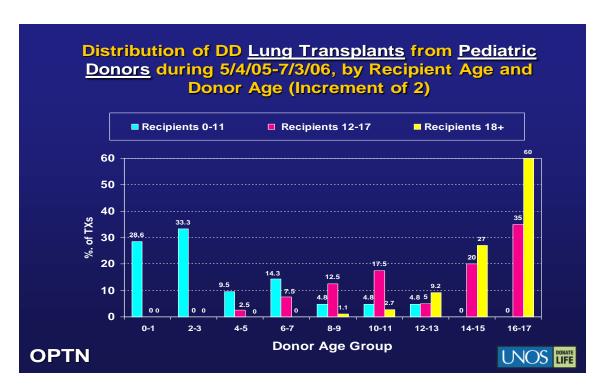


Figure 4: Deceased Donor (DD) Lung Transplants from Pediatric Donors from 5/4/05 through 7/3/06, by Recipient Age and Donor Age Groups.

In considering ways to modify the donor allocation polices to better serve the 0-11 year-old lung candidates, the Committee wanted to ensure that collapsing or combining current allocation groups (local offers and/or offers by geographic zones) would not negatively impact the 0-11 year olds or adolescents and adults awaiting lung transplant. Many 0-11 year old donor lung transplants for children ages 0-9 are the result of offers extend from as far as Zone B, as seen in Figure 5.

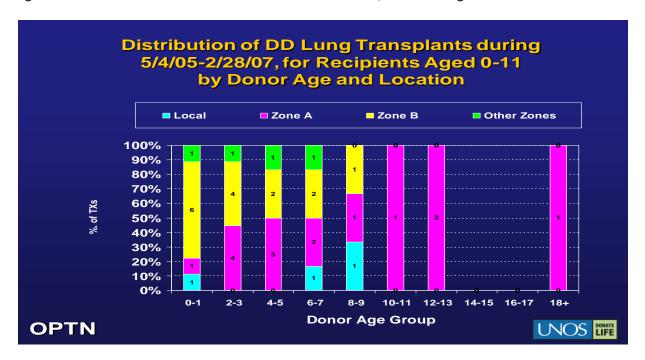


Figure 5: Distribution of Deceased Donor Lung Transplants during 5-4-05 through 2-28-07 for Recipients Aged 0-11 by Donor Age and Location

This indicated to the Committee that there is potential to make a difference in waiting list mortality by eliminating the stepwise process of offering organs locally before continuing offers by Zones A through E in a stepwise fashion. Collapsing these artificial divisions and making offers to a combined pool of local, Zone A and Zone B candidates for 0-11 year old donors will provide access to a broader group of candidates.

The Committee then set forth to develop a simple status based system that would allow it to rank this sickest children at the top of this expanded first round of offers. Pediatric lung programs were informally polled regarding all current and recent candidates to determine where they fell into the two categories outlined earlier in this proposal. While not as in depth as the lung allocation system used to rank adolescent and adult candidates, both pediatric and adult transplant pulmonologists polled on and both Committees felt that this simple status system would be an effective mechanism to prioritize allocation to the sickest candidates among the few younger candidates on the match run.

Expected Impact on Program Goals, Strategic Plan and Adherence to OPTN Final Rule:

The Pediatric Committee's proposal will address three of the OPTN/UNOS September 2006-2007 Strategic Plan goals:

Challenge 1 - Donor Shortage

Challenge 2 - Changing Allocation Principles

Challenge 3 - Reduce Variation in Access to Transplantation

The Committee's goal of offering these small pediatric lungs to the sickest young pediatric candidates first over a wider geographic area than what is currently used meets provisions of the Final Rule as outlined in §121.8(b) (2) and (3).

Plan for Evaluation of the Proposal:

The Pediatric and Thoracic Committees will review waiting list and transplant data for all ages to ensure that this change in allocation serves its intended purpose without negatively impacting adolescent or adult pre- or post-transplant outcomes.

- What questions/hypotheses are guiding the evaluation of the proposal? Answers to these should help determine whether or not the proposal is meeting its intended goal(s).
 - Have pediatric death rates on the lung waiting list decreased since policy change?
 - Have adolescent and adult death rates on the lung waiting list increased since policy change?
 - Have pediatric transplant rates on the lung waiting list increased since policy implementation?
 - Have adolescent and adult transplant rates on the lung waiting list decreased since policy change?
 - Are there more 0-11 lungs being utilized after policy change?
 - Have number and percent of 0-11 lung transplants increased since policy change?
 - Have number and percent of adult or adolescent lung transplants decreased since policy change?
 - o Has post-transplant survival changed since policy change?
- Policy Performance Measures: what specific data are going to be used to evaluate the proposal?

The following data will be provided:

- Waiting list number for 0-11 candidates by status after the policy change
- Waiting list death rates by age group before and after the policy change
- Waiting list transplant rates by age group before and after the policy change
- Number and percent of lungs under each disposition by age group before and after the policy change
- Distribution of deceased donor lung transplants by donor and recipient age groups and location before and after the policy change
- Distribution of deceased donor lung transplants in 0-11 recipients by donor and recipient age groups, location and status after the policy change
- Post-transplant patient survival by donor and recipient age groups before and after the policy change (<u>Note</u>: this will be provided when there is sufficient posttransplant follow-up information, i.e., after the policy is in place for 18 or 24 months)

• Time Line for Evaluation – Data will be evaluated every 6 months.

Additional Data Collection:

Additional data will be required to establish status classification for 0-11 year-old lung candidates. The Pediatric Heart-Lung Working Group is working with UNOS IT Development staff to integrate data collection into the current mechanism used by the LAS to collect the required and optional listing data elements. Several of these variables are already part of the clinical data required to assign LAS scores for adolescent and adult lung candidates. Many pediatric programs are already entering their 0-11 year-old candidates' clinical data related to the lung allocation score, though it is not required. The Pediatric Committee is currently studying the feasibility of adding elements required for the proposed status system that are not already captured in LAS, and making all status-related data mandatory for these 0-11 children. The Joint Subcommittee will consider feedback from IT Development staff and recommend a collection method when the Board considers this proposal.

This new status system would follow requirements for LAS, allowing programs to update their candidates' clinical data at any time they believe a change in candidate medical condition warrants such modification. Programs must update every candidate variable for each candidate at least once every six months. If at any time, more than six months have elapsed since the last six-month "anniversary" date of the candidate's initial listing without an update, then the candidate's status will as automatically revert to Status 2.

The Principles of Data collection cited for collection of this additional data to provide 0-11 candidates with a status on lung match runs will be used to:

- Develop transplant, donation and allocation policies, and
- Determine if Institutional Members are complying with policy.

Expected Implementation Plan:

Additional programming of UNetSM will be required to modify the lung allocation algorithm for 0-11 year-old donors. The Pediatric and Thoracic Organ Transplantation Committees will work together with UNOS IT Staff to develop and review specification documents as well as to determine priority among other committee policy changes awaiting implementation. Actual implementation dates will be determined based on project priorities at the time of BOD approval. As with LAS, centers will be able to enter data to establish status at least 3 months prior to go-live. Patients with missing data will be assigned Status 2. Because there are only 56 candidates less than 12 years old listed for lung transplant as of January 11, 2008, this transition should not incur a significant burden on transplant centers.

Communication/Education Plan:

If approved by the Board of Directors, the transplant community will receive information regarding new policy language via the Policy Notice that follows each Board meeting. Additional details regarding the final implementation date will be sent to members through a UNetSM Systems Notice

Monitoring and Evaluation:

OPOs and transplant centers will be expected to comply with this policy. UNOS Department of Evaluation and Quality (DEQ) staff will evaluate member compliance with this policy.

How members will be expected to comply with this policy

OPOs are expected to:

 Allocate lungs according to the match run sequence generated by the OPTN computer match system

Transplant centers are expected to:

- Enter accurate information about a lung candidate's clinical condition and status into UNet^{sm1}
- Maintain medical record documentation to support all information entered into UNetsm
- Provide documentation to support a candidate's listing criteria upon request

How OPTN/UNOS will evaluate member compliance with this policy

The UNOS Department of Evaluation and Quality (DEQ) staff evaluates member compliance with OPTN/UNOS Policies and Bylaws in different ways, including:

- Site Surveys of Transplant Centers and Organ Procurement Organizations
- Lung Review Board Administration
- Allocation Analysis.

These proposed changes will potentially affect all three areas. More specific details about OPTN/UNOS monitoring efforts will be available in the OPTN Evaluation Plan following approval and implementation of these policy changes. General information about compliance monitoring is provided below.

Impact on Site Survey Monitoring Process: During site surveys of lung transplant programs, UNOS staff currently verifies clinical data entered into UNetsm for lung transplant candidates for accuracy and compliance with applicable Policies and Bylaws. For example, to verify clinical data used to calculate a lung candidate's Lung Allocation Score (candidates >= 12 years old), UNOS staff compares the information entered into UNetsm to the medical record documentation. UNOS staff reports any discrepancies or potential policy violations that are identified during the site survey process to the transplant center. After receiving a response and corrective action plan (if applicable), UNOS staff forwards the survey results to the OPTN/UNOS Membership and Professional Standards Committee for review.

If this change is approved, UNetsm would be modified to collect information pertaining to the statuses described for lung candidates less than 12 years old. UNOS staff would modify monitoring efforts to incorporate a review of pediatric candidates (< 12 years old) listed at Status 1.

¹ UNetSM is the web-based electronic utility used by the OPTN contractor to conduct the business of the OPTN. UNetSM comprises the Match System, all software, applications and security architecture needed for the collection, modification, validation, reporting, management and redundancy of data associated with the tasks and activities of the OPTN.

Impact on Lung Review Board Monitoring Process: UNOS staff currently administers the Lung Review Board process to:

- ensure the transplant center's request is submitted to the Lung Review Board in a timely manner;
- facilitate the Lung Review Board in reviewing the transplant center's request in a timely manner;
- communicate the Lung Review Board's decision to the transplant center in a timely manner;
- ensure the lung candidate's status is updated according to the Lung Review Board's decision in a timely manner; and
- communicate with the organ specific committees regarding specific cases when required according to policy.

If this change is approved, UNetsm would be modified to include Lung Review Board requests for pediatric lung candidates less than 12 years old. UNOS staff would modify monitoring efforts to incorporate lung review board administration for candidates less than 12 years old.

Impact on Allocation Monitoring: If this change is approved, the computer match system operated by the OPTN will be updated to reflect the allocation sequence.

The computer match system operated by the OPTN:

- compares data entered into UNetsm for transplant candidates and organ donors;
- incorporates organ acceptance criteria specific to each candidate;
- eliminates candidates who are not suitable for the donor organ;
- ranks candidates according to approved OPTN policies; and
- produces a match run consisting of potential recipients in sequential order according to the priority defined by OPTN allocation policy.

OPOs are expected to allocate organs according to the match run generated by the OPTN computer match system. UNOS staff monitors organ allocations to ensure organs are allocated according to the match run sequence. When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of allocations and validates data entered into UNetsm for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

If this change is approved, UNOS staff will begin monitoring allocation of lungs to candidates under the age of 12 as part of routine allocation monitoring activities.

Policy Proposal:

The Pediatric and Thoracic Organ Transplantation Committees request your consideration and feedback on recommended modifications to policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation), and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation) as drafted below. Please note that numbering in the lung allocation policies is recommended to change from roman numerals to standard digits. Additionally, extraneous language has been removed for brevity. These suggested edits are to be considered as housekeeping and do not change the intent of these policies in any way.

Please note that final language regarding how clinical data used to establish status for 0-11 year olds will be developed by the Joint Subcommittee and sent to the Board of Directors when this proposal is considered.

3.7.6.2 <u>Candidates Age 0 - 11</u>. Candidates 0 – 11 years old are assigned priority for lung offers based upon waiting time. according to the status categories defined below. Within each status, candidates will be ranked by ABO according to Policy 3.7.8.2 and then by waiting time. Status 1 candidates will be ranked in descending order according to the length of time waiting time at that status. For Status 2 candidates, total waiting time (defined for this purpose as beginning when the candidate was added to the waiting list and ending when the lung match run was generate), will be used to rank candidates on the match run.

Status 1: candidates with one or more of the following criteria:

- Respiratory failure, defined as:
 - Full time Mechanical Ventilation;or,
 - Supplemental oxygen delivered by any means to achieve FiO₂ > 50% necessary to maintain oxygen saturation levels > 90%;

or,

- Arterial or Capillary PCO₂ > 50 mmHg.
- Refractory pulmonary hypertension, defined as:
 - Treatment failure (any of: suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate, cardiac index < 2 l/min/M², recurrent syncope or hemoptysis) while on 2 or more drugs for pulmonary hypertension;

or,

- o <u>Candidates with pulmonary vein</u> stenosis involving 3 or more vessels.
- Exceptional cases by prospective submission to a review board

Status 2: all candidates who do not meet the criteria for Status 1 will be listed as Status 2.

3.7.11 Sequence of Adult Donor Lung Allocation. Candidates age 12 and older awaiting a lung transplant whether it is a single lung transplant or a double lung transplant will be grouped together for adult (18 years old and older) donor lung allocation. If

one lung is allocated to a candidate needing a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from adult donors will first be offered to candidates age 12 and older, and then to candidates 0-11 years old. Lungs from adult donors will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

In summary, the allocation sequence for adult donor lungs is as follows:

- i. 1. First locally to Local ABO identical candidates age 12 and older according to Lung Allocation Score in descending order;
- ii. 2. Next, locally to Local ABO compatible candidates age 12 and older according to Lung Allocation Score in descending order;
- iii. 3. Next, locally to Local ABO identical Status 1 candidates 0 11 years old according to length of waiting time;
- iv. <u>4. Next, locally to Local</u> ABO compatible <u>Status 1</u> candidates 0 11 years old according to length of waiting time;
- v. 5. Local ABO identical Status 2 candidates 0 11 years old according to length of waiting time;
- vi. 6. Local ABO compatible Status 2 candidates 0 11 years old according to length of waiting time;
- vii. 7. Next, to ABO identical candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
- viii. <u>8.</u> Next, to ABO compatible candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
- ix. 9. Next, to ABO identical Status 1 candidates 0 11 years old in Zone A according to length of waiting time;
- x.10. Next, to ABO compatible Status 1 candidates 0 11 years old in Zone A according to length of waiting time;
- xi.11. ABO identical Status 2 candidates 0 11 years old in Zone A according to length of waiting time;
- xii.12. ABO compatible Status 2 candidates 0 11 years old in Zone A according to length of waiting time;
- xiii.13. Next, to ABO identical candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
- xiv.14. Next, to ABO compatible candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
- xv.15. Next, to ABO identical Status 1 candidates 0 11 years old in Zone B according to length of waiting time;

- xvi.16. Next, to ABO compatible Status 1 candidates 0 11 years old in Zone B according to length of waiting time;
- <u>xvii.17.</u> ABO identical Status 2 candidates 0 11 years old in Zone B according to length of waiting time;
- <u>xviii.18.</u> ABO compatible Status 2 candidates 0 11 years old in Zone B according to length of waiting time;
- xix.19. Next, to ABO identical candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
- xx.20. Next, to ABO compatible candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
- xxi.21. Next, to ABO identical Status 1 candidates 0 11 years old in Zone C according to length of waiting time;
- xxii.22. Next, to ABO compatible Status 1 candidates 0 11 years old in Zone C according to length of waiting time;
- <u>xxiii.23.</u> ABO identical Status 2 candidates 0 11 years old in Zone C according to length of waiting time;
- <u>xxiv.24.</u> ABO compatible Status 2 candidates 0 11 years old in Zone C according to length of waiting time;
- xxv.25. Next, to ABO identical candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
- xxvi.26. Next, to ABO compatible candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
- <u>xxvii.27.</u> Next, to ABO identical <u>Status 1</u> candidates 0 11 years old in Zone D according to length of waiting time;
- xxviii.28. Next, to ABO compatible Status 1 candidates 0 11 years old in Zone D according to length of waiting time.;
- <u>xxix.29.</u> ABO identical Status 2 candidates 0 11 years old in Zone D according to length of waiting time;
- <u>xxx.30.</u> ABO compatible Status 2 candidates 0 11 years old in Zone D according to length of waiting time;
- xxxi.31. Next, to ABO identical candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;
- <u>xxxii.32.</u> Next, to ABO compatible candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;
- **xxiii.33. Next, to ABO identical Status 1 candidates 0 11 years old in Zone E according to length of waiting time; and
- <u>xxxiv.34.</u> Next, to ABO compatible <u>Status 1</u> candidates 0 11 years old in Zone E according to length of waiting time.
- xxxv.35. ABO identical Status 2 candidates 0 11 years old in Zone E according to length of waiting time;
- <u>xxxvi.36</u>. ABO compatible Status 2 candidates 0 11 years old in Zone E according to length of waiting time;
- **3.7.11.1** Sequence of Pediatric Donor Lung Allocation. Candidates 0 11 years old awaiting a single or double lung transplant will be grouped together for allocation purposes. If one lung is allocated to a candidate waiting

for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant

Candidates 12 - 17 years old awaiting a single or double lung transplant will be grouped together for pediatric (0 - 17 years old) donor lung allocation. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from donors 0-11 years old will first be offered to candidates age 0-11; then to candidates age 12-17; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D, and finally to candidates in Zone E. In each of those—six—geographic areas, ϵC andidates will be grouped so that candidates those who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

- Offers for 0-11 year-olds will first be made to combined local, Zone A and Zone B candidates by status and waiting time. After adolescent and adult offers are completed through Zone B, offers will continue to these younger candidates in Zones C, D and E prior to adolescents and adults within in each zone.
- Offers for 12-17 year-olds will first be made to combined local and Zone A candidates according to lung allocation score in descending order after the completion of 0-11 year-old offers through Zone B. Once adult Zone A offers are completed, offers will continue to adolescent candidates in Zones B, C, D and E after the younger 0-11 candidates and before the adult candidates within each zone.
- Offers to adult candidates (18 years and older) will be made after the completion of 0-11 year old offers through Zone B and adolescent offers through Zone A. After local and Zone A adult offers are completed, offers will continue in Zones B, C, D and E after the completion of all pediatric offers within each zone.

In summary, the allocation sequence for lungs from donors 0<u>-</u>11 years old is as follows:

- i. First locally to ABO identical candidates 0 11 years old according to length of time waiting;
- ii. Next, locally to ABO compatible candidates 0 11 years old according to length of time waiting;
- 1. Combined local, Zone A and Zone B ABO identical Status 1 candidates 0-11 years old according to length of waiting time;
- 2. Combined local, Zone A and Zone B ABO compatible Status 1 candidates 0-11 years old according to length of waiting time;
- 3. Combined local, Zone A and Zone B ABO identical Status 2 candidates 0-11 years old according to length of waiting time;
- 4. Combined local, Zone A and Zone B ABO compatible Status 2 candidates 0-11 years old according to length of waiting time;
- Combined local and Zone A ABO identical candidates 12 17 years old according to Lung Allocation Score in descending order;
- 6. Combined Local and Zone A ABO compatible candidates 12 17 years old according to Lung Allocation Score in descending order;
- iii. Next, locally to ABO identical candidates 12 17 years old according to Lung Allocation Score in descending order;
- vii. Next, locally to ABO compatible candidates 12 17 years old according to Lung Allocation Score in descending order;
- viii. 7. Next, locally to Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
 - ix.8. Next, locally to Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
 - vii. Next, to ABO identical candidates 0 11 years old in Zone A according to length of time waiting;
 - viii. Next, to ABO compatible candidates 0 11 years old in Zone A according to length of time waiting;
 - ix. Next, to ABO identical candidates 12 17 years old in Zone A according to Lung Allocation Score in descending order;
 - x. Next, to ABO compatible candidates 12 17 years old in Zone A according to Lung Allocation Score in descending order;
 - x.9. Next, to ABO identical candidates 18 years old and older in Zone
 A according to Lung Allocation Score in descending order;
- xi.<u>10.</u> Next, to ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
 - xiii. Next, to ABO identical candidates 0 11 years old in Zone B according to length of time waiting;
 - xiv. Next, to ABO compatible candidates 0 11 years old in Zone B according to length of time waiting;
- xii.11. Next, to ABO identical candidates 12 17 years old in Zone B according to Lung Allocation Score in descending order;
- xiii. 12. Next, to ABO compatible candidates 12 17 years old in Zone B according to Lung Allocation Score in descending order;

- xiv.13. Next, to ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
- xv.14. Next, to ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
- xvi.15. Next, to ABO identical Status 1 candidates 0 11 years old in Zone C according to length of time waiting;
- xvii.16. Next, to ABO compatible Status 1 candidates 0 11 years old in Zone C according to length of time waiting;
- xviii.17. ABO identical Status 2 candidates 0-11 years old in Zone C according to length of waiting time;
 - 18. ABO compatible Status 2 candidates 0-11 years old in Zone C according to length of waiting time;
- xx.19. Next, to ABO identical candidates 12 17 years old in Zone C according to Lung Allocation Score in descending order;
- xxi.20. Next, to ABO compatible candidates 12 17 years old in Zone C according to Lung Allocation Score in descending order;
- xxii.21. Next, to ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;
- xxiii.22. Next, to ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
- xxiv.23. Next, to ABO identical Status 1 candidates 0 11 years old in Zone D according to length of time waiting;
- Next, to ABO compatible Status 1 candidates 0 11 years old in Zone D according to length of time waiting;
 - 25. ABO identical Status 2 candidates 0-11 years old in Zone D according to length of waiting time;
 - 26. ABO compatible Status 2 candidates 0-11 years old in Zone D according to length of waiting time;
- xxvii.27. Next, to ABO identical candidates 12 17 years old in Zone D according to Lung Allocation Score in descending order;
- <u>xxviii.28.</u> Next, to ABO compatible candidates 12 17 years old in Zone D according to Lung Allocation Score in descending order;
- xxix.29. Next, to ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
- XXX.30. Next, to ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
- **xxi.31. Next, to ABO identical Status 1 candidates 0 11 years old in Zone E according to length of time waiting;
- Next, to ABO compatible Status 1 candidates 0 11 years old in Zone E according to length of time waiting;
 - 33. ABO identical Status 2 candidates 0-11 years old in Zone E according to length of waiting time;
 - 34. ABO compatible Status 2 candidates 0-11 years old in Zone E according to length of waiting time;
- *** Next, to ABO identical candidates 12 17 years old in Zone E according to Lung Allocation Score in descending order;

- Next, to ABO compatible candidates 12 17 years old in Zone E according to Lung Allocation Score in descending order;
- XXXVII. 37. Next, to ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and

Lungs from donors 12-17 years old will first be offered to candidates age 12-17 years old; then to candidates age 0-11; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the compatible (but not identical) with that of the donor.

In summary, the allocation sequence for lungs from donors 12 - 17 years old is as follows:

- i-1. First locally to Local ABO identical candidates 12 17 years old according to Lung Allocation Score in descending order;
- ii.2. Next, locally to Local ABO compatible candidates 12 17 years old according to Lung Allocation Score in descending order;
- iii.3. Next, locally to Local ABO identical Status 1 candidates 0 11 years old according to length of time waiting;
- <u>iii.4.</u> <u>Local ABO compatible Status 1 candidates 0 11 years old</u> according to length of time waiting;
 - <u>5.</u> <u>Local ABO identical Status 2 candidates 0 11 years old according to length of time waiting;</u>
 - Local ABO compatible Status 2 candidates 0 11 years old according to length of time waiting;
- vi.7. Next, locally to Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
- vii.8. Next, locally to Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
- <u>viii.9.</u> Next, to ABO identical candidates 12 17 years old in Zone A according to Lung Allocation Score in descending order;
- <u>vix.10.</u> Next, to ABO compatible candidates 12 17 years old in Zone A according to Lung Allocation Score in descending order;
 - x.11. Next, to ABO identical Status 1 candidates 0 11 years old in Zone A according to length of time waiting;
- xi.12. Next, to ABO compatible Status 1 candidates 0 11 years old in Zone A according to length of time waiting;

- <u>ABO identical Status 2 candidates 0 11 years old in Zone A according to length of time waiting;</u>
 - <u>ABO compatible Status 2 candidates 0 11 years old in Zone A according to length of time waiting;</u>
- xiv.15. Next, to ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
- xv.16. Next, to ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
- xvi.17. Next, to ABO identical candidates 12 17 years old in zone B according to Lung Allocation Score in descending order;
- xvii.18. Next, to ABO compatible candidates 12 17 years old in zone B according to Lung Allocation Score in descending order;
- xviii.19. Next, to ABO identical Status 1 candidates 0 11 years old in Zone B according to length of time waiting;
- <u>xix.20.</u> Next, to ABO compatible <u>Status 1</u> candidates 0 11 years old in Zone B according to length of time waiting;
 - 21. ABO identical Status 2 candidates 0 11 years old in Zone B according to length of time waiting;
 - 22. ABO compatible Status 2 candidates 0 11 years old in Zone B according to length of time waiting;
- Next, to ABO identical candidates 18 years old and older in Zone
 B according to Lung Allocation Score in descending order;
- xxiii.24. Next, to ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
- xxiv.25. Next, to ABO identical candidates 12 17 years old in zone C according to Lung Allocation Score in descending order;
- **xv.26. Next, to ABO compatible candidates 12 17 years old in zone C according to Lung Allocation Score in descending order;
- xxvi.27. Next, to ABO identical <u>Status 1</u> candidates 0 11 years old in Zone C according to length of time waiting;
- <u>xxvii.28.</u> Next, to ABO compatible <u>Status 1</u> candidates 0 11 years old in Zone C according to length of time waiting;
 - 29. ABO identical Status 2 candidates 0 11 years old in Zone C according to length of time waiting;
 - 30. ABO compatible Status 2 candidates 0 11 years old in Zone C according to length of time waiting;
- XXX.31. Next, to ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;
- xxxi.32. Next, to ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
- xxxii.33. Next, to ABO identical candidates 12 17 years old in zone D according to Lung Allocation Score in descending order;
- <u>xxxiv.35.</u> Next, to ABO identical <u>Status 1</u> candidates 0 11 years old in Zone D according to length of time waiting;
- Next, to ABO compatible Status 1 candidates 0 11 years old in Zone D according to length of time waiting;

ABO identical Status 2 candidates 0 - 11 years old in Zone D 37. according to length of time waiting; 38. ABO compatible Status 2 candidates 0 – 11 years old in Zone D according to length of time waiting; Next, to ABO identical candidates 18 years old and older in Zone xxxviii.39. D according to Lung Allocation Score in descending order; and Next, to ABO compatible candidates 18 years old and older in xxxix.40. Zone D according to Lung Allocation Score in descending order. Next, to ABO identical candidates 12 – 17 years old in Zone <u>xxxx.41.</u> E according to Lung Allocation Score in descending order; xxxxi.42. Next, to ABO compatible candidates 12 - 17 years old in Zone E according to Lung Allocation Score in descending order; Next, to ABO identical Status 1 candidates 0 – 11 years old xxxxii.43. in Zone E according to length of time waiting; Next, to ABO compatible Status 1 candidates 0 – 11 years xxxxiii.44. old in Zone E according to length of time waiting; <u>45.</u> ABO identical Status 2 candidates 0 - 11 years old in Zone E according to length of time waiting; ABO compatible Status 2 candidates 0 - 11 years old in Zone E <u>46.</u> according to length of time waiting; Next, to ABO identical candidates 18 years old and older in xxxxvi.47. Zone E according to Lung Allocation Score in descending order; and xxxxvii.48. Next, to ABO compatible candidates 18 years old and older

in Zone E according to Lung Allocation Score in descending

order.